

201 KAR 8:016. Registration of dental laboratories.

RELATES TO: KRS 313.021, 313.022, 313.550

STATUTORY AUTHORITY: KRS 313.021(1)(a), (c), 313.022(1)(c), 313.080, 313.090, 313.100

NECESSITY, FUNCTION, AND CONFORMITY: KRS 313.021(1)(a) requires the board to govern dental laboratories. KRS 313.021(1)(c) requires the board to promulgate administrative regulations for any license or registration created by the board. KRS 313.022(1) requires the board to promulgate administrative regulations to prescribe a reasonable schedule of fees, charges, and fines. This administrative regulation establishes requirements for the issuance and renewal of dental laboratory registration with the board. This administrative regulation establishes fees for the issuance, renewal, and reinstatement of registrations of dental laboratories with the board.

Section 1. (1) Each commercial dental laboratory operating, doing business, or intending to operate or do business in the state shall register with the board and pay the fee established in Sections 4 and 8 of this administrative regulation.

(2) A dental laboratory shall be considered operating or doing business within this state if its work product is prepared pursuant to a written authorization originating within this state.

Section 2. The board shall not issue a registration to a commercial dental laboratory unless the applying dental laboratory is operated under the supervision of at least one (1) certified dental technician (CDT) or dentist licensed in this state in accordance with KRS 313.550.

Section 3. If the dental laboratory has violated any provision of KRS Chapter 313 or 201 KAR Chapter 8, the dental laboratory shall be subject to disciplinary action pursuant to KRS 313.080 and 313.100.

Section 4. Each commercial dental laboratory shall pay a fee of \$150 to the board before a registration shall be issued to the applicant.

Section 5. Upon the granting of a registration, the board shall assign to that laboratory a dental registration number. The laboratory registration number shall appear on all invoices or other correspondence of the laboratory.

Section 6. A dentist shall use only those services of a commercial dental laboratory that is duly registered with the board as required by this administrative regulation. A dentist shall include the registration number of the dental laboratory on the dentist's work order.

Section 7. Each commercial dental laboratory operating, doing business, or intending to operate or do business within the state shall submit an Application for Registration of Dental Laboratory or Renewal of Registration of Dental Laboratory to the board on a form provided by the board accompanied with the registration or renewal fee required. The application shall include:

- (1) The name, mailing address, phone number, and e-mail address of the laboratory;
- (2) The physical address of the laboratory if different from the mailing address;
- (3) The name and CDT number of the supervising CDT or the name and license number of the supervising dentist who is licensed in this state;
- (4) A statement that the laboratory meets the infectious disease control requirements under

Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC) of the United States Public Health Service;

(5) An acknowledgement by the supervising CDT or dentist who is licensed in this state that the laboratory will provide material disclosure to the prescribing dentist that contains the U.S. Food and Drug Administration registration number of all patient contact materials contained in the prescribed restoration in order that the dentist may include those numbers in the patient's record; and

(6) An acknowledgement by the supervising CDT or dentist who is licensed in this state that he or she will disclose to the prescribing dentist the point of origin of the manufacture of the prescribed restoration. If the restoration was partially or entirely manufactured by a third-party provider, the point of origin disclosure shall identify the portion manufactured by a third-party provider and the city, state, and country of the provider.

Section 8. Each commercial dental laboratory registered with the board shall be required to renew its registration before July 31 each year by completing and submitting a Renewal of Registration of Dental Laboratory form and paying a fee of \$150.

Section 9. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Application for Registration of Dental Laboratories", June 2014; and

(b) "Renewal Application for Registration of Dental Laboratories", March 2014.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Dentistry, 312 Whittington Parkway, Suite 101, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. through 4:30 p.m. This material is also available on the board's Web site at <http://dentistry.ky.gov>. (40 Ky.R. 2385; Am. 2679; 41 Ky.R. 257; eff. 6-18-2014.)